

REMARKS

Reconsideration of the captioned application as amended herewith is respectfully requested.

A petition for a one month extension of time to file this Amendment is attached herewith.

The Office Action rejected claims 1 - 14 under 35 USC §112, First Paragraph, as not enabling; rejected claims 1 – 14 under 35 USC §112, second paragraph, as being indefinite; rejected claims 1 – 5 as anticipated under 35 USC §102(b) by GB 2,256,139 (“139”); rejected claims 1 – 14 under 35 USC §103 as unpatentable over United States Patent No. 5,456,851 to Liu (“Liu”), United States Patent No. 5,536,742 to Mason, ('Mason'), individually or in combination, and further in combination with United States patent No.: 5,688,496 to Fost (“Fost ‘496”). Claims 1 - 14 remain pending in the application after entry of this amendment.

Claim one was amended to highlight one particular art-known body or hair cleansing product ingredient. Support for this amendment may be found in the Specification as originally filed at, for example, page 5, lines 11 – 14, and as such do not introduce new matter into the application under 37 CFR 1.121.

Attached hereto is a marked-up version of the changes made to the claims by the current amendment. The attached page is captioned, “Version with markings to show changes made.”

Claims 1 – 14 Are Enabling Under 35 USC §112, First Paragraph

Claims 1 - 14 stand rejected under 35 USC §112, First Paragraph, as not enabling “for antifungal inhibiting ergosterol biosynthesis” and ‘for formulations other than shampoos.’ Applicants respectfully disagree for the reasons that follow.

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According to the Office Action, the Specification allegedly "does not provide adequate support for drugs other than ketoconazole and formulations other than shampoos." As a result, the Office Action concluded that the "claims must be limited to shampoo compositions containing specific components and containing ketoconazole." Applicants respectfully maintain that the Specification, as originally filed, enables one skilled in the art to make and use the claimed invention directed to compositions comprising "antifungal inhibiting ergosterol biosyntheses" (including but not limited to ketoconazole) for a variety of "body or hair cleansing" products (including but not limited to shampoos).

The law is clear that it is not necessary to disclose every operative example of a broad class of agents that are a component of a claimed composition so long as one skilled in the art is fully apprised by the specification of what the invention is and how to use it. In re Boiler, 141 USPQ 740 (CCPA 1964). Applicants respectfully submit that one skilled in the art would fully appreciate upon reading the Specification that three components of the present invention as presently claimed include: a) an antifungal that inhibits fungal ergosterol biosynthesis; b) an amphoteric phospholipid; and c) a surfactant. Applicants further respectfully submit that one skilled in the art would fully appreciate upon reading the Specification as to how the claimed invention may be made and used.

According to the Specification, "antifungals inhibiting ergosterol biosynthesis" as claimed herein include those antifungals that, when present with the claimed phospholipid, produce a mutual synergistic effect on the inhibition of the growth of dermatophyte fungi, in particular, the species associated with dandruff and seborrheic dermatitis, i.e. *Malassezia furfur* (*Pityrosporum ovale*), but also other fungi such as *Epidermophyton*, *Microsporum*, *Trichophyton* species associated with, for example, dermatophytosis, pityriasis versicolor and the like. Specification, page 4, line 31 to page 5, line 1. Particular examples of the first component, "antifungals inhibiting ergosterol biosynthesis," are clearly set forth in the specification on page 3, lines 20 to

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35 and include "azole(s), allylamines(s) or mixtures thereof." Examples of azoles, such as econazole, miconazole, itraconazole, fluconazole, and elubiol, in addition to ketoconazole, are expressly set forth. Specification, page 3, lines 21 – 25. Further, examples of allylamines, such as terbinafine, naftifine are also expressly set forth. Specification, page 3, lines 23 – 24. Page 8, lines 19 – 29 of the Specification further provides an exemplary shampoo formulation in which from about 0.1% to about 2% of antifungal may be used.

It is not necessary to describe every last detail of an invention by working examples or otherwise. See Ex parte Wolters, 214 USPQ 735 (Bd. Pat. App. 1979). Although the examples set forth in the Specification are directed to shampoos containing either ketoconazole or elubiol as the claimed antifungal component, Applicants expressly provide that it would "be evident to a person skilled in the art that the combinations [i.e. the claimed antifungal and claimed amphoteric phospholipid], can be utilized just as well in other surfactant-containing body and hair cleansing products". See Specification, page 2, line 37 – page 3, line 4. Applicants respectfully submit that one skilled in the art would readily know that such body cleansing products may be made by incorporating carriers, which are commonly added to such body cleansing products such as, e.g. "surfactants, e.g. anionic, cationic, non-ionic or amphoteric surfactants such as to form a cleansing lotion; one or more soap materials such as sodium tallowate, sodium cocoate, sodium palm kernelate or sodium palmitate such as used to formulate a bar soap; thickening agents such as carboxymethyl cellulose used to form a gel," and the like, in known amounts to the components of the composition claimed herein. See, for example, WO 96/29983, page 18, lines 16 – 25 ("Other such carriers include water, lower C1 to C4 alcohols such as ethanol or isopropanol, polyalcohols such as glycerine or propylene glycol.")

The amount of antifungals used in the claimed composition is from about .1% to about 2% (w/w), see Specification, page 3, lines 28 – 30, and the amount of phospholipids is from about 0.04% to about 10% (w/w). See Specification, page 4,

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lines 14 – 16. Moreover, as set forth above, the antifungals and the phospholipids are preferably present in quantities producing a mutual synergistic effect on the inhibition of the growth of dermatophyte fungi, Specification, page 4, lines 31 – 33, and particularly within the weight:weight ratio of about 5:1 to about 1:150 (antifungal:pyrithione). The types and amounts of other optional ingredients, such as conditioners, and the like are also disclosed throughout pages 5, line 10 to page 8, line 30, and many of the same optional ingredients are those commonly used in body cleansing formulations. Cf. WO 96/29983.

The Specification further discloses how to use the invention as presently claimed. As set forth in the Specification on page 9, lines 21 – 28, the claimed composition is “to be applied topically to the affected body parts at regular intervals, in particular from at least once weekly to about one daily. Preferably they are employed more often in the beginning of the treatment, e.g. from about 4 to 7 times a week, and less frequently in a later stage when the desired effect has been obtained and relapse is to be prevented (e.g. once or twice a week).” (emphasis added) Clearly, one skilled in the art would readily appreciate that suitable applications for the claimed composition are not limited to just shampoos for the scalp, but rather also include other cleansing products to be applied to any affected body part.

Given the fact that a patent specification is not intended to be a product specification, In re Gay, 135 USPQ 311 (CCPA 1962), and the fact that one skilled in the art would readily appreciate without undue experimentation as to how to make and use the claimed invention in formulations other than shampoos, Applicants respectfully submit that the rejection of claims 1 – 14 under 35 USC §112, First Paragraph, have been overcome and should be withdrawn.

**The Rejection to claims 1 – 14 Under 35 USC § 112,
Second Paragraph Should be Withdrawn**

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Claims 1 - 14 stand rejected under 35 USC §112, Second Paragraph, as being indefinite. Applicants respectfully disagree for the reasons that follow.

The term "synthetic" has been deleted from claim 1 for purposes of rendering the claim more definite.

The phrase "art-known body and hair cleansing product ingredients" was replaced by the term "surfactant," which is one example of such ingredients, for purposes of rendering the claim more definite.

Claims 2, 8, and 9 were amended for purposes of placing the claim into proper Markush format.

The "one or more of a surfactant" language was deleted from claim 7.

The abbreviations MIPA," "DEA," and "MEA" were deleted from claims 8 and 9, and their corresponding chemical names were written out in full. Support for this amendment may be found in the Specification as originally filed at, for example, page 5, lines 34 – 37.

In view of the above amendments to the claims, Applicants respectfully submit that the rejection of claims 1 – 14 under 35 USC §112, Second Paragraph, has been overcome and should be withdrawn.

The Rejection of Claims 1 – 5 under 35 USC §102(b) as Anticipated by GB 2256139 Should Be Withdrawn

Claims 1 – 5 stand rejected under 35 USC §102(b) as anticipated by GB 2256139. Applicants respectfully disagree for the reasons that follow.

GB 2256139 expressly states that "[n]o surface active agents... are required thereby and additional side effect problems commonly associated with their use are thus avoided." Therefore, the compositions of GB 2256139 do not contain and expressly teach away from the use of any surfactants, which are an element of claim 1

Rejections under 35 USC §102 are proper only when the claimed subject matter is identically disclosed or described in the prior art. In re Marshall, 198 USPQ 344

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(CCPA 1978). In other words, to constitute an anticipation, all material elements recited in a claim must be found in one unit of prior art. Id. The exclusion of a claimed element from a prior art reference is enough to negate anticipation under 35 USC §102 by that reference. Atlas Powder Co. v. E.I. Du Pont de Nemours & Co., 224 USPQ 409 (Fed. Cir. 1984).

Therefore, since GB 2256139 fails to disclose or suggest an element of Applicants' claim 1, i.e. a surfactant, Applicants respectfully submit that the rejection of claim 1 under 35 USC §102(b) has been overcome and should be withdrawn.

Claims 2 – 4, which are dependent upon claim 1 and incorporate all of its limitations therein, are likewise also patentable over GB 2256139 in view of the above.

GB 2256139 further fails to disclose or suggest the use of the claimed antifungal and the claimed phospholipid 'in quantities producing a mutual synergistic effect on the inhibition of the growth of *Malassezia furfur*' as claimed in claim 4. Therefore, since GB 2256139 also fails to disclose or suggest an element of Applicants' claim 4, i.e. use of the claimed antifungal and the claimed phospholipid 'in quantities producing a mutual synergistic effect on the inhibition of the growth of *Malassezia furfur*', Applicants respectfully submit that the rejection of claim 4 under 35 USC §102(b) has further been overcome and should be withdrawn.

**The Rejection of Claims 1 – 14 under 35 USC §103(a)
as Being Unpatentable Over Liu and/or Mason, and
Further Over Fost Should Be Withdrawn**

Claims 1 – 14 stand rejected under 35 USC §103(a) as being unpatentable over Liu and/or Mason individually or in combination, further in combination with Fost '496. Applicants respectfully disagree for the reasons that follow.

As stated in the Office Action, both Liu and Mason neither disclose nor suggest the use of phospholipids, let alone the use of the particular amphoteric phospholipids as claimed in claim 1.

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According to the Office Action, the phospholipids for Fost '496 possess properties such as foaming, cleansing, and the like. However, Fost '496 neither discloses nor suggests that its phospholipid compounds also possess antibacterial/antifungal properties. The Office Action then relied upon a different Fost reference, i.e., Fost '348, for the disclosure of a very specific phospholipid that possesses antibacterial/antifungal properties. However, those specific phospholipids of Fost '348 have a structure that is different from the phospholipids disclosed in Fost '496. Therefore, Applicants respectfully submit that there is neither a disclosure nor a suggestion in Fost '348 to include its antifungal/antibacterial phospholipids in the antifungal-containing compositions of Liu or Mason because: 1) Fost '348 is silent regarding the foaming, cleansing, conditioning properties of its antifungal/antibacterial phospholipids; 2) Fost '496 does not disclose that its foaming, cleansing phospholipids, which differ in structure from the phospholipids of Fost '348, also possess antifungal/antibacterial properties; and 3) there is no disclosure or suggestion in Liu or Mason to further include an antimicrobial agent, let alone the particular antibacterial/antifungal phospholipids of Fost '348. Moreover, given the fact that the compositions of Liu and Mason already include an antifungal component, Applicants respectfully submit that there is no disclosure or suggestion in either Liu or Mason to further include yet another antifungal compound, let alone the particular antibacterial/antifungal phospholipids of Fost '348.

Not only have Applicants discovered that an increased proportion of patients suffering from dandruff or seborrheic dermatitis responded to the novel claimed composition (see Specification, page 2, lines 1 – 14 and page 3, lines 8 - 10), but Applicants have also unexpectedly found that the claimed combination exhibits superior synergistic properties against *M. furfur* *in vitro* as set forth in Example 7 on pages 13 – 15 of the Specification. (FIC values less than one are indicative of a synergistic interaction between the ketoconazole and the Phospholipid PTC.)

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In sum, not only is there a lack of disclosure or motivation to combine the references as proposed in the Office Action, but also Applicants have unexpectedly found that the particular antifungal components and the particular amphoteric phospholipid components claimed herein possess superior, synergistic effects on the inhibition of *M. furfur* growth. In view of the above, Applicants respectfully submit that claim 1 is patentable over Mason and/or Liu and further in combination with Fost '496, and that the rejection of claim 1 under 35 USC §103(a) has been overcome and should be withdrawn.

Claims 2 – 14, which depend upon claim 1 and incorporate all of its limitations therein, are likewise patentable over Mason and/or Liu and further in combination with Fost '496, and that the rejection of these claims under 35 USC §103(a) has been overcome and should be withdrawn.

Moreover, claim 3, which is directed to a particular phospholipid, is neither disclosed nor suggested in either of the two Fost references. In particular, the phospholipids of these Fost references do not have the acyl group as does the claimed phospholipid.

In view of the fact that Applicants unexpectedly found that the claimed active ingredients unexpectedly possessed a synergistic effect on the growth of *M. furfur* as set forth above, Applicants respectfully submit that none of the cited references disclose or suggest the creation of a composition containing the claimed active ingredients in quantities producing "a mutual synergistic effect on the inhibition of the growth of *Malassezia furfur*" as claimed in claim 4.

Because none of the references disclosed the combination of the claimed antifungal with the claimed amphoteric phospholipid, let alone the above mentioned synergistic effect exhibited by such a combination, Applicants further respectfully submit that none of the prior art references disclose or suggest the percentage amount of each claimed component as set forth in claim 5.

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In addition, in view of the fact that none of the prior art references disclosed or suggested the claimed composition of claim 1, Applicants further respectfully submit that the process for making such a composition set forth in claim 14 is also neither disclosed nor suggested in the prior art.

In view of the arguments set forth above for claim 1 and the additional arguments set forth above for the dependent claims, Applicants further respectfully submit that the rejection of claims 3, 4, 5, and 14 under 35 USC §103(a) has been overcome and should be withdrawn.

Conclusion

It is submitted that the foregoing amendments and remarks place the case in condition for allowance. A notice to that effect is earnestly solicited.

In the event that all of the claims are not in condition for allowance, Applicants respectfully request for an interview with the Examiner before the preparation of the next Office Action.

Respectfully submitted,

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Att.

1 month extension of time
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Version with Markings to Show Changes Made

IN THE CLAIMS:

1. (Amended) A body or hair cleansing composition comprising
 - (a-1) one or more antifungals inhibiting fungal ergosterol biosynthesis as a first active ingredient,
 - (a-2) a [synthetic] amphoteric phospholipid as a second active ingredient, and
 - (b) [art-known body or hair cleansing product ingredients as a carrier] at least one surfactant.
2. (Amended) A composition according to claim 1 wherein the antifungal inhibiting fungal ergosterol biosynthesis is an azole selected from the group [comprising] consisting of ketoconazole, econazole, elubiol, miconazole, itraconazole, fluconazole, [or] and a mixture thereof, or is an allylamine selected from the group [comprising] consisting of terbinafine, naftifine, [or] and a mixture thereof.
7. (Amended) A shampoo according to claim 6 [wherein the art known shampoo ingredients comprise] further comprising one or more of [a surfactant,] a foaming agent, a thickener sufficient to give the final formulation a viscosity in the range of 4,000 to 9,000 mPa.s at room temperature, a preservative, an anti-oxidant, and acid or base or buffer sufficient to give the shampoo a pH in the range of from about 4 to about 10.
8. (Amended) A shampoo according to claim 7 [comprising one or more surfactants] wherein the surfactant is selected from the group [comprising] consisting of sodium C14-16 olefin sulfonates, sodium lauryl sulfate, sodium laureth sulfate, cocamidopropylamine oxide, lauryl amine oxide, lauramido [DEA] di-ethanol amide, cocamidopropyl betaine, lauryl dimethyl betaine, cocodimethyl sulphopropyl betaine, sodium cocoyl sarcosinate, disodium oleamido [MIPA] mono-isopropanol amide

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sulfosuccinate, disodium cocamido [MIPA] mono-isopropanol amide sulfosuccinate,
disodium laureth sulfosuccinate, cocoamphocarboxylglycinate, disodium oleamido
[MEA] mono-ethanol amide sulfosuccinate, amine glycimates, amine propionates and
amine sultanes, and mixtures thereof.

9. (Amended) A shampoo according to claim 7 wherein the foaming agent is
[selected from the group of] a fatty acid mono-and di- alkanolamide[s consisting]
selected from the group consisting of cocamide [MEA] mono-ethanol amide, cocamide
[DEA] di-ethanol amide, oleamide [MEA] mono-ethanol amide, oleamide [DEA] di-
ethanol amide, and mixtures thereof.